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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,980	04/11/2002	Jens Berthelsen	PHRM-0373	9431

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,980	BERTHELSEN ET AL	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-23,26-30 and 32-57* is/are pending in the application.

4a) Of the above claim(s) *1-12,14-18,26-30,32-47,49-52 and 55-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19, 21-23, 48, 53 and 54* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/22/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of claims 1, 15, 21 and 27, in the paper of 10/25/2004, is acknowledged. Claims 1-12, 14-23, 26-30 and 32-57 are still at issue and are present for examination.

Applicant's election with traverse of Group II, claims 19-23, 48, 53 and 54 drawn to a tankyrase homology protein, in the paper of 10/25/2004, is acknowledged. The traversal is on the ground(s) that applicants disagree with the previous distinction that each of the "groups lack the same or corresponding special technical feature..." however applicants do not state reasons for their disagreement. Thus the reasons presented in the previous office action stand.

Applicants further argue that no serious burden would be imposed upon the Examiner by combining several of the groups, for example the nucleic acid (Group I) and protein (Group II) groups.

This is not found persuasive because while the searches for the groups do overlap, they are not coextensive. This argument is not found persuasive on the basis that the many additional and distinct databases would have to be searched in combining the nucleic acid and protein groups and this would result in serious burden.

Further, the different searches can be demonstrated by the different class/subclasses that would have to be searched for each of the distinct groups. For example, search of Group I would require search of subclass 536/23.2 and search of Group III would require search of subclass 530/350.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that on 1/6/2005, the examiner informed applicant's representative, Gwilym J.O. Attwell, that the previous restriction requirement mistakenly included claims 40-44 in group II, when in fact they should have been included with Group I. Applicant's representative acknowledged this and stated that he still maintained his election of Group II, now claims 19-23, 48, 53 and 54 drawn to a tankyrase homology protein.

Claims 1-12, 14-18, 26-30 and 3247, 49-52 and 55-57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in the paper of 10/25/2004.

Claim Objections

Claims 20 and 21 are objected to because of the following informalities: Claim 21 recites "an amino acid at least 90% homologous to SEQ ID NO: 5". It is believed that this should recite "an amino acid **sequence** at least 90% homologous to SEQ ID NO: 5".

Claim 29 depends from rejected claim 19.

Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/22/2004 was considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21-23, 48, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19, 21-23, 48, 53 and 54 are drawn to all isolated polypeptides encoded by a nucleic acid molecules comprising: a nucleotide sequence selected from SEQ ID NO: 3 or 4 or fragments thereof, a sequence at least 90% homologous to SEQ ID NO: 3 or 4 or a fragment thereof, a sequence that encodes a polypeptide comprising SEQ ID NO: 5 or a fragment thereof, or a sequence that encodes a polypeptide comprising an amino acid sequence at least 90% homologous to SEQ ID NO: 5 or a fragment thereof, wherein said nucleic acid molecule encodes at least a portion of a tankyrase homolog protein (claim 19), and those polypeptides which comprise an amino acid sequence at least 90% homologous to SEQ ID NO: 5 with no defined function (claims 21-23) and composition and kits comprising said polyeptides (claims 48, 53 and 54).

The specification, however, only provides the representative species of polypeptides having the amino acid sequence of SEQ ID NO: 5 encompassed by the claimed genus. There is no disclosure of any particular structure to function/activity

relationship in the disclosed species. The specification also fails to describe additional representative species of these nucleic acid molecules and host cells by any identifying structural characteristics or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of polypeptide molecules that are claimed is a large variable genus with potentiality of comprising many different proteins. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims. The specification discloses only one species of the claimed genus (i.e. the sequence encoding SEQ ID NO: 5) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 19, 21-23, 48, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those polypeptides having the amino acid sequence of SEQ ID NO: 5, which have the ability to ADP-ribosylate TRF1, does not reasonably provide enablement for those polypeptide molecules which have an undefined function or activity. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 19, 21-23, 48, 53 and 54 are so broad as to encompass any isolated protein encoded by a nucleic acid comprising a nucleotide sequence selected from SEQ ID NO: 3 or 4 or fragments thereof, a sequence at least 90% homologous to SEQ ID NO: 3 or 4 or a fragment thereof, a sequence that encodes a polypeptide comprising SEQ ID NO: 5 or a fragment thereof, or a sequence that encodes a polypeptide comprising an amino acid sequence at least 90% homologous to SEQ ID NO: 5 or a fragment thereof, wherein said nucleic acid molecule encodes at least a portion of a tankyrase homolog protein having any activity or function. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the utility of the DNA encoding the extremely large number of polypeptides broadly encompassed by the claim. It would require undue experimentation of the skilled artisan to make and use any of the polypeptide molecules comprising any specified amino acid fragment, its complement or its homolog with any activity. The specification is limited to teaching the use of those nucleic acids which encode partial polypeptides of a tankyrase homolog which have the ability to ADP- ribosylate TRF1 as enzymatic catalysts and provides no guidance with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptide, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure, the claimed invention would require undue

experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any isolated polypeptide encoded by any DNA encoding any fragment of a Tankyrase homolog having any activity or function. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 23 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (Science 282: 1484, 1998).

Smith et al teach the identification and cloning of Tankyrase, a poly(ADP-ribose) polymerase (PARP) protein with homology to ankyrins. The polypeptide encoded by

the nucleic acid that is taught by Smith et al. has a best local similarity score greater than 80% to the instantly disclosed protein having the amino acid sequence of SEQ ID NO: 5. The polypeptide taught by Smith et al. is encoded by a nucleic acid molecule which comprises a nucleotide sequence which is a fragment of SEQ ID NO: 4. Smith et al. additionally recombinantly express tankyrase and show that it has PARP enzymatic activity. Therefore claims 19, 23 and 48 are anticipated by Smith et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al.

As discussed above, Smith et al. teach the identification, cloning and expression of Tankyrase, a poly(ADP-ribose) polymerase (PARP) protein with homology to ankyrins. Smith et al. further teach that Tankyrase is localized to telomeres and binds to telomeric repeat binding factor-1 and may act as a negative regulator of telomere length maintenance.

One of ordinary skill in the art would have been motivated to express the Tankyrase protein as part of a kit comprising and an additional components as well as instructions as to its use would have been obvious as a diagnostic for the study of DNA

damage repair. Therefore, claims 53 and 54 would have been *prima facie* obvious at the time of applicants invention.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
1/5/2005